REMARKS/ARGUMENTS

Claims 58-113 are pending in the present application. Claims 58-113 stand rejected. Reconsideration of the present application is respectfully requested in view of the following remarks.

The rejection of claims 58-66, 68-73, 75-85, 87-92, 94-97, 100-101 and 105-107 under 35 U.S.C. 103(a), as being unpatentable over the M.V.I.-12 package insert in view of each of Lundberg, Greff and an alleged admission by applicant, is respectfully traversed for the reasons set forth below.

Initially, applicant does not concede that the Examiner has provided sufficient evidence that the M.V.I.-12 package insert was actually published prior to the filing date of the present patent application, which was August 3, 2001. Without addressing all of the circumstantial evidence provided by the Examiner to support his position that the insert was actually "published" prior to the filing date of the present patent application, applicant reserves the right to address this issue on appeal, if necessary. The use herein of the term "primary reference" or "reference" to refer to the M.V.I.-12 package insert should not be interpreted as an admission that the insert is actually prior art under 35 U.S.C. 102.

In addition, the Examiner has acknowledged that the M.V.I.-12 product is an intravenous infusion formulation and not an animal food additive. The Examiner's position is that, even though the present claims clearly state that the formulations defined by the claims are animal food additives, patentable weight is not given to the preamble/intended use of the composition "because the claims are functionally complete without any such limitation". It is respectfully submitted that this argument is incorrect in that the "animal food additive" limitation in the present claims is a not just an "intended use" but is part of the definition of the claimed product. Further, the word "food" is defined in most dictionaries as something that is eaten or ingested, which is clearly the meaning intended in the present application. There is absolutely no teaching whatsoever in the M.V.I.-12 package insert that the formulation would be suitable for oral administration. In fact, the package insert teaches away from oral administration by

warning that the product is suitable for intravenous infusion only. It would be improper to use this formulation as an animal food additive. For all of these reasons, it is respectfully submitted that the Examiner's position is incorrect and should be withdrawn.

In addition to the above arguments, it is respectfully submitted that the M.V.I.-12 package insert describes a formulation that is not even comparable to the formulation of the present claims, regardless of whether the formulation is to be ingested or delivered intravenously. Specifically, the formulations of present claims 58-66, 68-73, 75-85, 87-92 and 94-97 require that the animal food additive contain from 10% to 60% by weight of a vitamin component selected from the group consisting of:

(i) precursors of Vitamin A;

(ii) precursors of Vitamin E;

(iii) a mixture of precursors of Vitamin A and precursors of Vitamin E;

(iv) a mixture of precursors of Vitamin A and Vitamin D3;

(v) a mixture of precursors of Vitamin E and Vitamin D3; and

(vi) a mixture of precursors of Vitamin A, precursors of Vitamin E, and Vitamin D3.

According to these claims, with the exception of Vitamin D3, the other substances are all precursors to the indicated vitamins. The Examiner has indicated that the M.V.I.-12 package insert formulation contains a precursor to Vitamin A and identifies "retinol" as that precursor. It is respecfully submitted that retinol is not a precursor to Vitamin A. Instead, retinol is the dietary form of Vitamin A. Thus, M.V.I.-12 contains Vitamin A itself, not a precursor to Vitamin A. Further, the formulation of M.V.I.-12 (vial 1; 5 ml total volume) contains only 1 mg of Vitamin A, which is 0.02% by weight and 10 mg of the Vitamin E precursor, which is 0.20% by weight. These amounts are not even of the same order of magnitude of the minimum amount in the animal food additives of claims 58-97 of the present application (i.e., 10% by weight or 15% by weight for some claims). One of the many reasons for why the M.V.I.-12 formulation contains very different amounts of the vitamins or precursors to the vitamins than the animal food additive of the present claims is that the M.V.I.-12 formulation is an intravenous

formulation and is not intended to be ingested, as are the animal food additives of the present claims. However, regardless of the reason for the differences in amounts of the vitamins or vitamin precursors, it is clear that the formulation described in the M.V.I.-12 package insert does not describe a formulation that is even remotely similar to the formulation of present claims 58-97. Optimization of the amounts of components in a formulation does not include changing the amounts of the components by an order of magnitude or more, especially when those components are the active components in the formulation.

The secondary references (Lundberg and Greff) and the alleged admission by applicant cited by the Examiner provide no teachings that would allow the use of Vitamin A itself, rather than a precursor of Vitamin A, or allow the use of 10 to100 times (or more) of the active ingredients than are disclosed in the M.V.I.-12 package insert.

With respect to claims 100-101 and 105-107, these claims require that the animal food additive contain from 10% to 60% by weight of a vitamin component selected from the group consisting of:

(i) a precursor of Vitamin A;

(ii) a precursor of Vitamin E;

(iii) a mixture of a precursor of Vitamin A and a precursor of Vitamin E;

(iv) a mixture of a precursor of Vitamin A and Vitamin D3;

(v) a mixture of a precursor of Vitamin E and Vitamin D3; and

(vi) a mixture of a precursor of Vitamin A, a precursor of Vitamin E, and Vitamin D3.

The same arguments that were set forth above concerning claims 58-66, 68-73, 75-85, 87-92 and 94-97, apply to these claims also.

Although applicant has not specifically addressed the Examiner's characterization of the teachings of the secondary references and alleged admission by applicant as set forth in the Office Action, this does not mean that applicant agrees that the Examiner's characterization is accurate or that the secondary references are properly combinable with the primary reference.

Applicant does not believe that there is any reason to address these issues at the present time because, even assuming arguendo that everything the Examiner has said about the secondary references and admission are correct, the teachings of the primary reference are so deficient that they cannot be overcome by the inclusion of the teachings of the secondary references. Applicant reserves the right, should it become necessary at a later point in time, to address the proper characterization of the secondary references and alleged admission and/or the appropriateness of the combination of the secondary references with the primary reference.

In view of the above, it is respectfully submitted that the Examiner has not established a prima facie case of obviousness.

The rejection of claims 74, 93, 98 and 99 under 35 U.S.C. 103(a) as being unpatentable over the M.V.I.-12 package insert, Lundberg, Greff and the alleged admission by applicant as applied above and further in view of the Multi-12 formulation, is respectfully traversed for the reasons set forth below.

Applicant reserves the right to argue in the future that the Examiner has not provided sufficient evidence to prove that the Multi-12 formulation descriptions were actually published before the filing date of the present application and/or that any formulations that were being publically used prior to the invention date or filing date of the present patent application actually had the same formulation that is shown in the written description cited by the Examiner.

Initially, for the same reasons as set forth above concerning the M.V.I.-12 formulation, it is respectfully submitted that the animal food additives claimed in the present claims cannot be rendered obvious by intravenous formulations such as Multi-12.

However, regardless of the type of formulation (food additive or intravenous), the Multi-12 formulation does not overcome the deficiency of the M.V.I.-12 formulation concerning the amount of the active ingredients. Unlike the M.V.I.-12 formulation, the Multi-12 formulation contains a precursor to Vitamin A. However, the amount of the precursor to Vitamin A is 3300 IU or 1 mg, which is 0.02% by weight of the formulation. The amount of Vitamin D3 in the Multi-12 formulation is 200 IU or 5 micrograms, which is 0.0001% by weight of the formulation. Thus, the total amount of these precursors is 0.0201% or about 500 times less than

the minimum of 10% by weight required by claims 74 and 93. Optimization of the amounts of components in a formulation does not include changing the amounts of the components by an order of magnitude or more, especially when those components are the active components in the formulation.

As discussed above, the other secondary references (Lundberg, Greff and applicant's alleged admission), even if they were properly combinable with the primary reference and contained all of the teachings asserted by the Examiner, add no teachings that would overcome the deficiencies of the primary reference.

In view of the above, it is respectfully submitted that the Examiner has not established a prima facie case of obviousness.

With respect to claims 98 and 99, these claims require the presence of from 1% to 6% by weight of Vitamin D3. As the Examiner has acknowledged, the M.V.I.-12 package insert formulation does not contain Vitamin D3. To overcome this deficiency, the Examiner cited the Multi-12 formulation, which does contain Vitamin D3, as a secondary reference. It is respectfully submitted that the Multi-12 formulation contains 200 IU or 5 micrograms of Vitamin D3. This corresponds to 0.0001% by weight of the Multi-12 formulation or 10,000 times less than the minimum of 1% by weight required in claims 98 and 99. As discussed earlier, optimization of the amounts of components in a formulation does not include changing the amounts of the components by an order of magnitude or more, especially when those components are the active components in the formulation.

As discussed above, the other secondary references (Lundberg, Greff and applicant's alleged admission), even if they were properly combinable with the primary reference and contained all of the teachings asserted by the Examiner, add no teachings that would overcome the deficiencies of the primary reference.

In view of the above, it is respectfully submitted that the Examiner has not established a prima facie case of obviousness.

The rejection of claims 67 and 86 under 35 U.S.C. 103(a) as being unpatentable over the

M.V.I.-12 package insert, Lundberg, Greff and applicant's alleged admission as applied to claims 58-66, 68-73, 75-85, 87-92, 94-97, 100-101 and 105-107, and further in view of Scialpi, is respectfully traversed for the reasons set forth below.

Applicants respectfully submit that the Scialpi patent is not properly combinable with the other cited documents, especially the primary reference. The Scialpi patent teaches the production of water-insoluble beadlets. This disclosure is clearly unrelated to the aqueous solutions of M.V.I.-12 and the liquid formulations of the present claims. Further, it is respectfully submitted that even if the Scialpi patent was found to be properly combinable with the other cited documents, that combination would not overcome the deficiencies of the primary reference that have been addressed above.

In view of the above, it is respectfully submitted that the Examiner has not established a prima facie case of obviousness.

The rejection of claims 102-104 and 108-113 under 35 U.S.C. 103(a) as being unpatentable over the M.V.I.-12 package insert, Lundberg, Greff and applicant's alleged admission as applied above, and further in view of Boussouira et al., is respectfully traversed for the reasons set forth below.

The teachings of the Boussouira et al. patent are limited to compositions to be applied to the skin or hair. The compositions are not to be ingested or supplied intravenously. Accordingly, the teachings of Boussouira et al. are simply irrelevant to the compositions of the present invention and are not properly combinable with the M.V.I.-12 document. Although the Boussouira et al. patent teaches that retinol and retinyl propionate are equivalent retinoids for application to external surfaces of the body for specific purposes, such a teaching cannot be used to support a position that the same substances are necessarily equivalent for compositions to be ingested or supplied intravenously. Such a substitution could easily cause the death of the animal to which the composition is provided, since externally applied compositions will almost always affect the animal differently than compositions taken internally. The same is true of formulations that are for ingestion when compared to formulations that are for I.V. administration. Many substances that can be safely administered by oral ingestion will kill or

harm the animal if supplied intravenously. For the above reasons, it is respectfully submitted that the Boussouira et al. patent cannot be combined with the other documents cited by the Examiner in the manner proposed by the Examiner.

In addition, even if the Boussouira et al. patent is found to be properly combinable with the other cited documents, it does not overcome the deficiencies in the disclosure of the M.V.I.-12 package insert that have been addressed above. Specifically, claims 102-104 and 108-113 all require at least 10% by weight of the recited vitamin component. The M.V.I.-12 formulation contains only 0.02% by weight of Vitamin A and no Vitamin D3. Even if the retinyl propionate of the Boussouira et al. patent was substituted for the retinol of the M.V.I.-12 formulation, the amount of the retinyl propionate would still be grossly deficient. Further, with respect to claims 108-113, the formulation would still contain no Vitamin D3. Optimization of the amounts of components in a formulation does not include changing the amounts of the components by an order of magnitude or more, especially when those components are the active components in the formulation. Further, optimization does not include adding components that are not present in the formulations of the prior art.

In view of the above, it is respectfully submitted that the Examiner has not established a prima facie case of obviousness.

Reconsideration of the present application and a favorable action concerning claims 58-113 is respectfully requested.

Respectfully submitted,
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